

Accuracy of Two Indirect Bonding Transfer Methods—
A Three-Dimensional, In-vivo analysis

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Dedication

This thesis is dedicated to my incredible mother, Duree Gyllenhaal, for her unending love, understanding, and encouragement. I could never be where I am today without you.

Abstract

Background: Recent literature has suggested that indirect bonding results in more accurate bracket placement. However, this more ideal positioning is of no use to the orthodontist unless the indirect bracket set-up is transferred accurately to the patient's dentition. This study aims to investigate the positional integrity of the indirect bonding transfer method of two commercially available tray types.

Materials and Methods: Eighteen patients were randomly assigned to either a transparent tray light-cure or an opaque tray chemical-cure indirect bonding system. A total of 129 teeth were analyzed for the transparent tray group and 99 teeth for the opaque tray group. An intraoral scanner was used to generate three-dimension .stl models of each indirect set-up ("pre-transfer" model) and each corresponding in-vivo bracketed patient arch ("post-transfer" model). A comparison software was used to superimpose these models based on a surface best-fit algorithm. Bracket position differences were measured in three translational and three rotational planes of space to the nearest 1 μm . Statistical analysis was performed to compare the pre- and post-transfer bracket position, to detect any directional patterns of error, and to compare the transparent and opaque tray systems.

Results: The indirect bonding transfer was found to be accurate for the data as a whole and for each tray type individually ($p < 0.0001$). Final bracket position tended to be slightly more buccal and more occlusal for both groups compared to the set-up. This error was clinically insignificant but was more pronounced for the opaque tray group.

Conclusions: Both indirect bonding methods transfer bracket position accurately in actual clinical use.

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Introduction

Modern orthodontics, because it largely utilizes the pre-adjusted bracket and straight-wire theory, requires very accurate bracket placement in order to achieve ideal alignment of the teeth.^{1,2} The decision regarding where to place each bracket is made considering tooth anatomy, root position, and the desired final occlusion. Improper bracket placement may complicate treatment because it results in the need to reposition brackets or place wire bends to compensate for inaccuracies in bracket positioning. Therefore, orthodontists aim to place the brackets as ideally as possible at the initial bonding appointment.

The traditional method of placing brackets on the teeth is via direct bonding, in which the orthodontist places each bracket on its corresponding tooth chair-side using a bracket placement instrument. This method of bonding brackets directly to the teeth involves some inherent barriers to precise bracket placement. Most notably, visibility is limited by the cheeks, tongue, saliva, and even isolation tools; this is especially true for posterior teeth. Therefore, important landmarks such as long axis and marginal ridges may be difficult to visualize because the teeth can only be viewed from certain angles. In addition, the operator may feel rushed or stressed due to risk of moisture contamination or patient behavior during bonding, which may further impair precise bracket placement. All these factors together make ideal bracket positioning difficult to achieve chair-side.^{3,4}

Indirect bonding has been theorized to improve bracket positioning. This method involves placing brackets onto a stone model of the patient's dentition, then transferring the bracket set-up to the patient's teeth using custom-made trays. Using this approach,

visualization for bracket placement is improved because teeth can be viewed from all angles when the model is held in the hand. Additionally, there is the opportunity to draw reference lines onto the cast—for example, lines demarcating the height of contour and marginal ridges of the teeth. Patient anatomy and behavior no longer distract from bracket placement, and there is no rush to finalize positioning due to risk of moisture contamination.^{3,4}

Several studies have shown that bond strength and bracket failure rate are similar in indirect and direct bonding⁵⁻⁷. An additional advantage of indirect bonding compared to direct bonding is reduced chair-side time^{8,9}, which may result in increased patient comfort. The major disadvantages of the indirect bonding technique are increased laboratory time and cost and technique sensitivity of the method^{4,10}. However, some authors argue that the additional laboratory tasks required to make the indirect bonding trays offer an opportunity for better use of office downtime.³

Generally, it seems that the literature supports the idea that indirect bonding results in more ideal bracket placement⁸⁻¹³. However, this more ideal placement is of no use to the orthodontist unless the indirect bracket set-up is transferred accurately to the patient's dentition. Some practitioners have questioned the accuracy of the transfer method in duplicating the intended bracket position onto the patient's teeth chair-side. It is feasible that discrepancies may arise due to inaccurate models, distortion of tray material, improper seating of the trays, or soft tissue interferences. If practitioners are to use the indirect bonding method with confidence, they must be sure of the integrity of the bracket transfer process.

Review of the Literature

Several studies have compared the accuracy of bracket placement between direct and indirect bonding.⁹⁻¹³ Results are mixed and vary for different teeth and measurements. Generally speaking, it seems that indirect bonding may be more precise than direct bonding, especially for certain teeth (e.g. maxillary and mandibular canines).

Aguirre et al⁹ performed an in-vivo split-mouth design study in which each half of a patient's dentition was randomly assigned to either direct or indirect bonding by the same operator. Bracket position was compared between the direct bonding and indirect bonding techniques and also to a pre-determined "ideal" bracket position for each type of tooth. The results showed that neither indirect nor direct bonding results in perfectly "ideal" bracket placement onto the teeth. However, the indirect bonding technique resulted in more ideal vertical placement on maxillary canines and mandibular second premolars, and more ideal angular placement on maxillary and mandibular canines.

In the same study, the researchers also investigated bond strength, bracket failure rate, and time required for each bonding procedure. To analyze bond strength, they purposely bonded brackets to teeth that would later be extracted. Once the teeth had been extracted, they utilized a shear bond strength-testing device on the brackets. They found no statistically significant difference in bond strength between the two methods. There was also no statistically significant difference in bracket failure rate between the two methods within the first three months of treatment. In regards to the clinical time required for each technique, indirect bonding involves significantly less time chair-side but significantly more total time when factoring in laboratory time compared to direct

bonding. Specifically, chair-side time required was 42.18 minutes for direct bonding and 23.91 minutes for indirect bonding. However, indirect bonding required an additional 29.82 minutes of laboratory time, for a total of 53.73 minutes for the entire procedure.

Koo et al.¹⁰ found similar results. In their in-vitro study, they utilized stone models for indirect bonding and stone models to simulate direct bonding on mannequins. Vertical, mesiodistal, and angular bracket position were measured directly on the bonded stone models. The bracket positions were compared between the two methods and also to an “ideal” set-up on a stone model. This study also found that neither method was able to achieve perfectly ideal bracket position. However, they found that indirect bonding resulted in more ideal vertical positioning of brackets on upper right second premolars and lower left central incisors, more ideal mesiodistal position on lower central incisors, and more ideal angular positioning on upper right lateral incisors. Overall, they found that indirect bonding resulted in better vertical bracket placement.

Shpack et al.¹¹ performed an in-vitro study comparing indirect and direct bonding for both labial and lingual bonding. They utilized ten sets of stone models for indirect bonding and ten sets of stone models to simulate direct bonding on mannequins. For each method, five models were assigned to labial bonding and the other five to lingual bonding. They analyzed bracket position by determining rotation deviation and torque error directly on the bonded stone models. Rotation deviation was measured using a microscope to determine the horizontal divergence between the tooth’s long axis and the vertical axis of the bracket slot. Torque error was measured using a torque geometric triangle to determine the angle between the occlusal plane and the vertical axis of the

bracket slot. The researchers found that errors in torque and rotation were decreased two-fold (labial bonding) to three-fold (lingual bonding) when using an indirect bonding technique. Contradictory to other studies, the researchers found this result to be significant for all teeth in the mouth, not just for specific teeth. The difference was most pronounced for torque error of the mandibular right lateral incisor in the lingual group, torque error of the maxillary left second premolar in the labial group, rotation deviation of the maxillary left canine in the lingual group, and rotation deviation of the maxillary left first premolar in the labial group.

Other studies have shown no difference in bracket positioning between the two methods. For instance, Hodge et al.¹² performed a randomized clinical trial using a split mouth study design to investigate the accuracy of direct vs. indirect bonding. They found no significant differences in vertical, horizontal, or angular position when each of the two groups were compared to an “ideal” set-up. However, the method of comparison seemed prone to error as it involved tedious superimposition of photos of the ideal setup with photos of a model made from an alginate impression of the direct or indirect setup.

One drawback of several of these studies is the use of a mannequin to simulate direct bonding, which eliminates some of the inherent barriers to bracket placement discussed previously including patient behavior and anatomy. Other limitations are the methods used for bracket position analysis—for example, some studies relied on photographs to determine bracket position. While the researchers attempted to standardize angulation and magnification of the photos, photographic comparison is likely not the most reliable method to use for measurements made on such a small scale.

Direct measurement or measurement on physical or virtual models would provide a more accurate assessment of bracket position.

While there have been several studies performed to compare the accuracy of direct versus indirect bonding, there have been far fewer studies investigating whether or not the indirect setup is accurately transferred to the patient's teeth. As mentioned above, the more ideal positioning of brackets with indirect bonding is of no use to the orthodontist unless the indirect bracket setup is transferred accurately to the patient's dentition.

Wendl et al.¹³ tested the accuracy of the indirect bonding transfer method using extracted teeth embedded in acrylic to simulate a patient's dentition. Although they found no significant differences in bracket positioning between the indirect setup and the final result, it could be argued that these results are not clinically applicable because the transfer was performed in vitro. Additionally, the bracket position comparison relied partially on superimposed photographs of the indirect bracket set-up and photographs of the final bracket position on the extracted teeth.

A recent study performed by Lee¹⁴ may be more clinically salient as the indirect bracket transfer was performed in vivo. Furthermore, the bracket position comparison was performed based on digital superimpositions of the pre- and post-transfer bracket position on each tooth. The comparison was on a much more sensitive scale—the software used was able to detect differences to the nearest 1 μm . The aforementioned study detected small but clinically insignificant differences in bracket positioning between the indirect setup and the final result. Clinical significance was defined as a

discrepancy greater than 0.5mm linearly or 2 degrees angularly. Importantly, the study determined the directional bias of the bracket positioning discrepancies. It was found that brackets positioned with their particular indirect bonding method tended to be more buccal and gingival in the patient compared to the indirect setup.

All of the studies cited above investigated only one indirect bonding transfer method. Currently, there are numerous indirect bonding in-house tray systems available on the market. Furthermore, there has been a recent rise in digital indirect bonding systems that deliver laboratory fabricated trays. Most orthodontists utilizing an indirect bonding system likely assume that any of these tray systems should be reliable. Literature investigating this assumption is necessary.

A recent study by Castilla et al.¹⁵ investigated the transfer accuracy of five indirect bonding methods in vitro. In the study, the indirect bracket set-ups were transferred to a second set of stone models. The five transfer tray methods investigated were: transparent VPS, opaque putty VPS, single vacuum-form, double vacuum-form, and VPS plus vacuum-form. The results of that study showed that all bracket discrepancies were relatively small, and that VPS trays had consistently higher accuracy in reproducing bracket position compared to vacuum-form trays.

To our knowledge, there has been no in-vivo study investigating the positional integrity of the indirect bonding transfer method of more than one tray type. An in-vivo study using a precise method for the comparison of bracket position in multiple tray types would be useful to provide further evidence for the positional integrity and generalizability of the indirect bonding transfer method.

Research Question: Does the indirect bonding transfer method accurately duplicate the indirect bracket placement setup when transferred to the patient's dentition in vivo?

Specific Aims:

1. To compare bracket position of an indirect setup on a stone model of the patient's dentition ("pre-transfer") to bracket position on the patient's dentition after indirect bonding ("post-transfer") in three translational and three rotational dimensions.
 - Null hypothesis: There is no difference between pre-transfer and post-transfer bracket position.
2. If differences in position exist, to identify directional patterns of error.
 - Null hypothesis: There is no predictable directional pattern of error in bracket position differences.
3. To compare bracket transfer error between two different transfer tray systems: a transparent silicone/VPS light-cure system (Ultradent Opal, South Jordan, UT, USA) versus an opaque putty VPS chemical-cure system (3M ESPE, Saint Paul, MN, USA).
 - Null hypothesis: There is no difference in bracket transfer error between the two systems.

Materials and Methods

This study received approval from the University of Minnesota's Institutional Review Board for human subjects research (study number 1312M46265). Informed consent was obtained from all patients and from parents in the case of minor patients. Informed assent was obtained from patients under the age of 18.

Subjects:

Eighteen patients were recruited from the University of Minnesota's graduate orthodontic clinic (61% male, mean age 20.2 years) based on the following inclusion criteria: patients were required to 1) be treatment planned for indirect bonding of the maxillary arch, mandibular arch, or both; and 2) be in full permanent dentition, second and third molars excepted. Patients were excluded if they had extractions before bonding or actively erupting teeth as there would be risk for tooth movement between time of the impression and time of the bonding.

All patients were randomly assigned an identity number. Subjects were randomized to one of two indirect bonding systems: either Emiluma/Lumiloc transparent silicone/VPS tray light-cure system (Ultradent Opal, South Jordan, UT, USA) or Express STD opaque VPS putty tray chemical-cure system (3M ESPE, Saint Paul, MN, USA). Eight patients were assigned to the transparent tray system and ten to the opaque tray system. For the transparent tray system, a total of 11 arches and 131 teeth were bonded; 2 bracket failures occurred leaving 129 teeth to be analyzed. For the opaque tray system, a total of 12 arches and 101 teeth were bonded; 2 bracket failures occurred leaving 99 teeth to be analyzed.

Study procedures:

For each subject, an alginate impression of the dentition was obtained no more than two weeks before the bonding appointment. The impression was poured in stone and the models were trimmed and all bubbles were removed. Reference lines were drawn on the models if desired; for example, a line demarcating the height of contour and long axis of each tooth and a line drawn from the mesial to distal marginal ridge. A diluted separator solution was applied to each model and allowed to dry. Each patient's treating resident positioned brackets on each tooth to be bonded using a bracket system of their choice and Transbond XT light cure adhesive paste (3M Unitek, Saint Paul, MN, USA) as the adhesive agent (Figure 1). Models were light-cured in a Maxi-Light light cure box (Select Dental Manufacturing Company, Farmingdale, NY, USA) for 10 minutes.



Figure 1: Example of bracket placement on an indirect set-up.

For the transparent trays, a thin layer of Emiluma transparent silicone was applied over the brackets using a dispensing gun. Subsequently, a thicker layer of Lumaloc transparent VPS was applied to form the body of the tray. Paper arch templates were used to form the shape of the tray (Figure 2). For the opaque trays, Express STD VPS putty system was used to fabricate the trays. Equal sized portions of catalyst and base putty were mixed thoroughly, then quickly formed into a cylindrical shape. The putty was then placed on the occlusal surface of the cast then formed over the teeth and brackets into the shape of a tray (Figure 3).

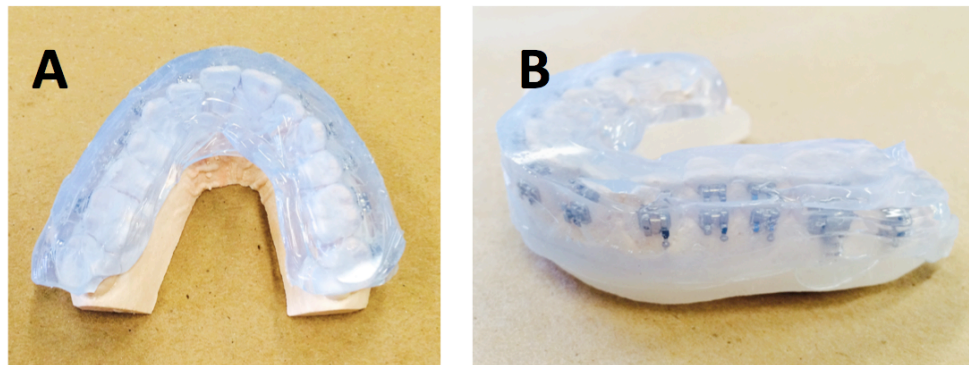


Figure 2: Transparent indirect bonding trays. (A) Occlusal and (B) side views.

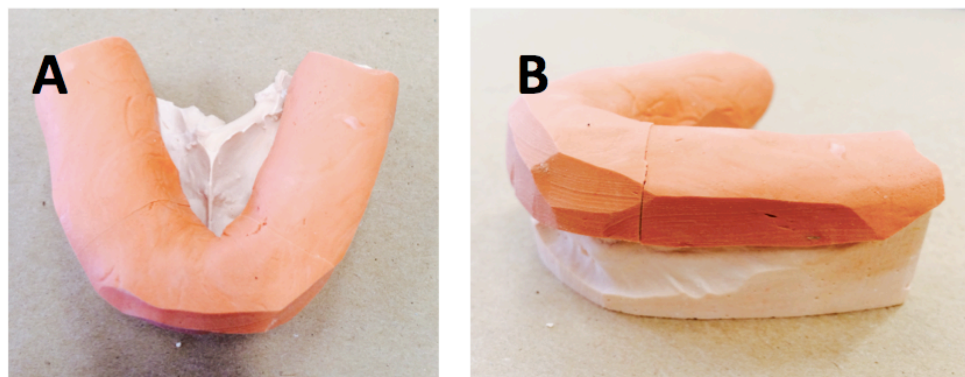


Figure 3: Opaque indirect bonding trays. (A) Occlusal and (B) side views.

For both tray types, the trays were allowed to set completely for 10 minutes then placed in room temperature water for 30 minutes to allow the bracket bases to detach from the casts. The trays were gently removed from the casts and then placed back in the light-cure box for 5 minutes to ensure complete cure of the composite bracket base. Excess tray material was removed with a scalpel. Finally, the trays were sectioned. In cases where molar brackets were not applied, trays were trimmed into quadrants by sectioning between the central incisors. In cases where molar brackets were applied (first and/or second molars), trays were trimmed into sextants by sectioning distal to the canines.

At the bonding appointment, each patient's teeth were isolated, pumiced, and etched with 35% phosphoric acid gel. A bond-enhancing primer was then applied to each tooth to be bonded and also to the back of each custom bracket base. For the transparent tray system, Opal Seal light-cure primer/sealant (Ultradent Opal, South Jordan, UT, USA) was used. For the opaque tray system, Maximum Cure chemical-cure primer/sealant (Reliance Orthodontic Products, Itasca, IL, USA) was used. Immediately after the primer was applied, trays were seated over the teeth and secured in place with light finger pressure (Figure 4). For the transparent tray system, each tooth was light cured with the tray in place for 15 seconds (Figure 4). For the opaque tray system, set was achieved via chemical cure by leaving each tray over the teeth for six minutes. Once full cure was complete, all trays were gently removed beginning on the lingual. For the transparent tray system, each tooth was light cured again for an additional five seconds after tray removal. Any bracket failures during tray removal and cleanup were recorded.

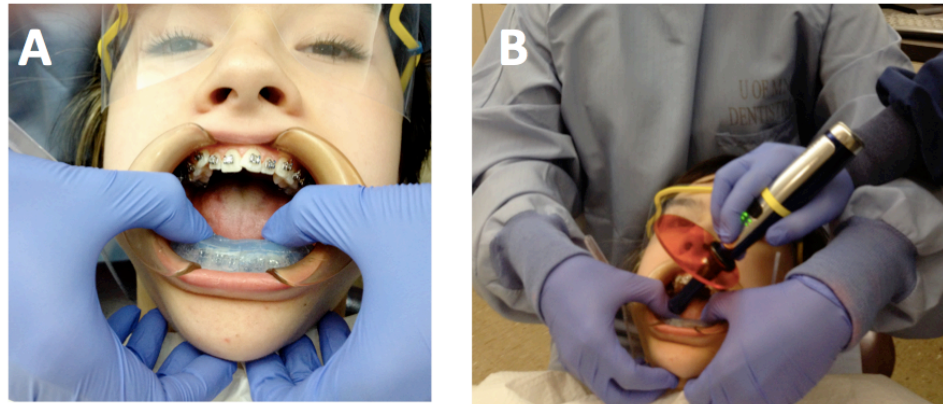


Figure 4: Chairside indirect bonding procedure.

The Lava Chairside Oral Scanner (3M Unitek, Saint Paul, MN, USA) was used to scan both the indirect setup (“pre-transfer”) and the final bracket position in the patient’s mouth (“post-transfer”) (Figure 5). The indirect setup model was scanned after the bracket position was finalized and secured by light-cure, but before the tray was fabricated. Full arch scans were taken of the patient’s dentition immediately after the brackets were transferred and cured but before the wire was placed in and tied.

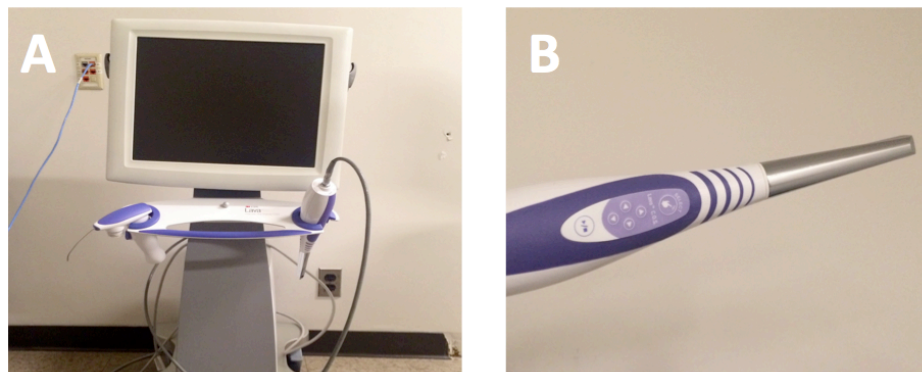


Figure 5: Lava Chairside intraoral scanner (3M Unitek, Saint Paul, MN, USA)

To quantify any operator error that may have been involved with the scanning and analysis of the models, two upper and two lower bracketed stone models were scanned twice each with a weeklong washout period between the two scans. Theoretically, the 3D .stl models generated from these scans should have been identical. Therefore, any measured differences in bracket position should be due to scanning or operator error.

Data Analysis

The scanned images were digitized and saved as three-dimensional stereolithography (.stl) files. Emodel Compare 9.0 software (GeoDigm Corporation, Falcon Heights, MN, USA) was used to prepare and superimpose the scans of each pre-transfer and post-transfer model (Figure 6). Global superimposition of the entire arch was then performed by 50 iterations of closest point matching at 1-mm surface increments.

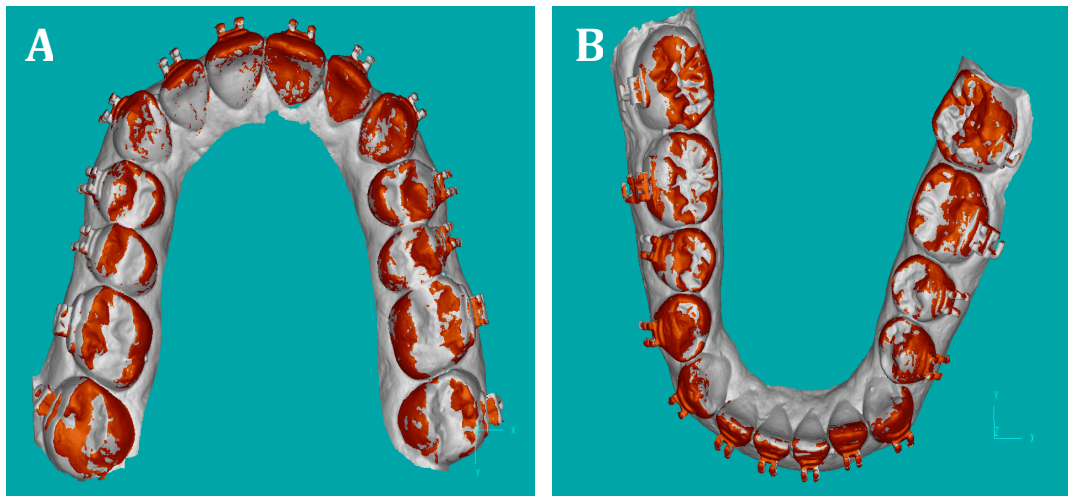


Figure 6: Three-dimensional superimposition of pre-transfer (gray) and post-transfer (orange) models using a best-fit algorithm for the surface area of the models.

It was recognized that the presence of the bracket likely affected the superimposition of the models. For this reason, an analysis was performed to determine the percentage of surface area occupied by bracket material versus tooth material (Figure 7). It was calculated that 19.6% of the maxillary arch and 21.0% of the mandibular arch was occupied by bracket material. Because the majority of the superimposed surface area was of tooth structure, it was assumed that the surfaces of the teeth would override the surfaces of the brackets during the superimposition process. This assumption was verified by visual analysis of each superimposition. A more even distribution of gray and orange indicated a good surface match, whereas isolated colors indicated a poor surface match.

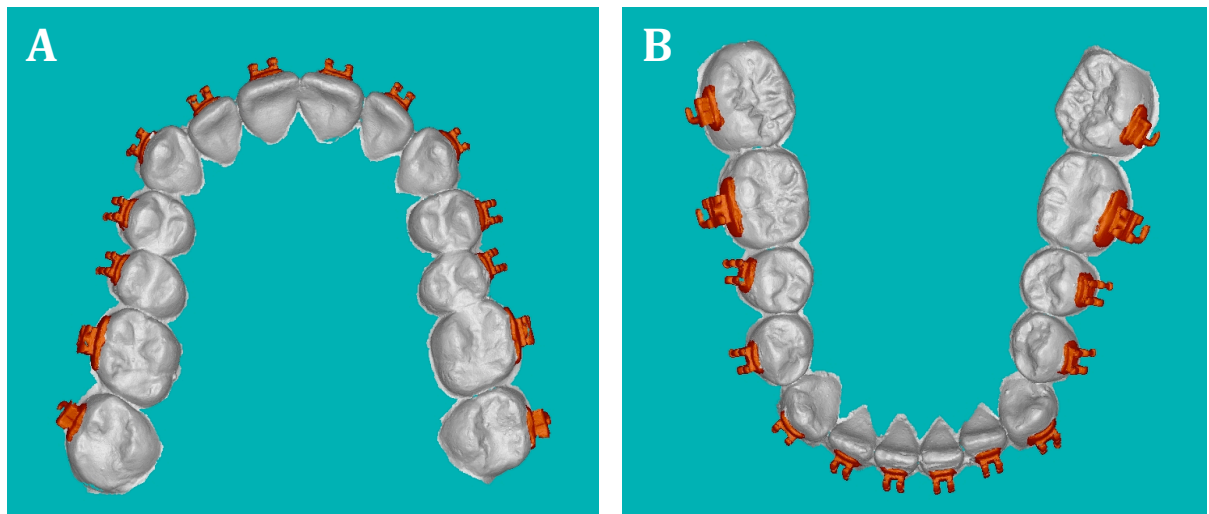


Figure 7: Surface area analysis to determine the percentage of model surface area occupied by bracket material (orange) versus tooth material (gray).

Next, a coordinate system consisting of an x, y, and z-axis was registered manually to each bracket. The x-axis represented the mesiodistal dimension and is depicted in red; the y-axis represented the buccolingual dimension and is depicted in green; finally, the z-axis represented the occlusogingival dimension and is depicted in blue (Figure 8).

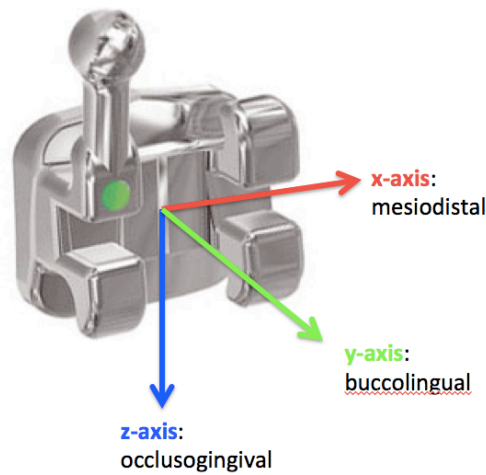


Figure 8: Bracket coordinate system. A three-dimensional coordinate system consisting of an x, y, and z-axis was registered to each bracket.

The placement of the axis onto each bracket was accomplished as follows. The intersection of the three axes (0,0,0) was placed on the surface of the center of the bracket slot. The x-axis was aligned mesiodistally to be parallel with the horizontal portion of the slot. The z-axis was aligned occlusogingivally to be parallel with the vertical portion of the slot. Finally, the y-axis was aligned to be perpendicular to the base of the bracket slot, such that the xz-plane was flush with the surface of the slot. For molar brackets, the axis was centered on the surface of the molar tube (Figure 9).

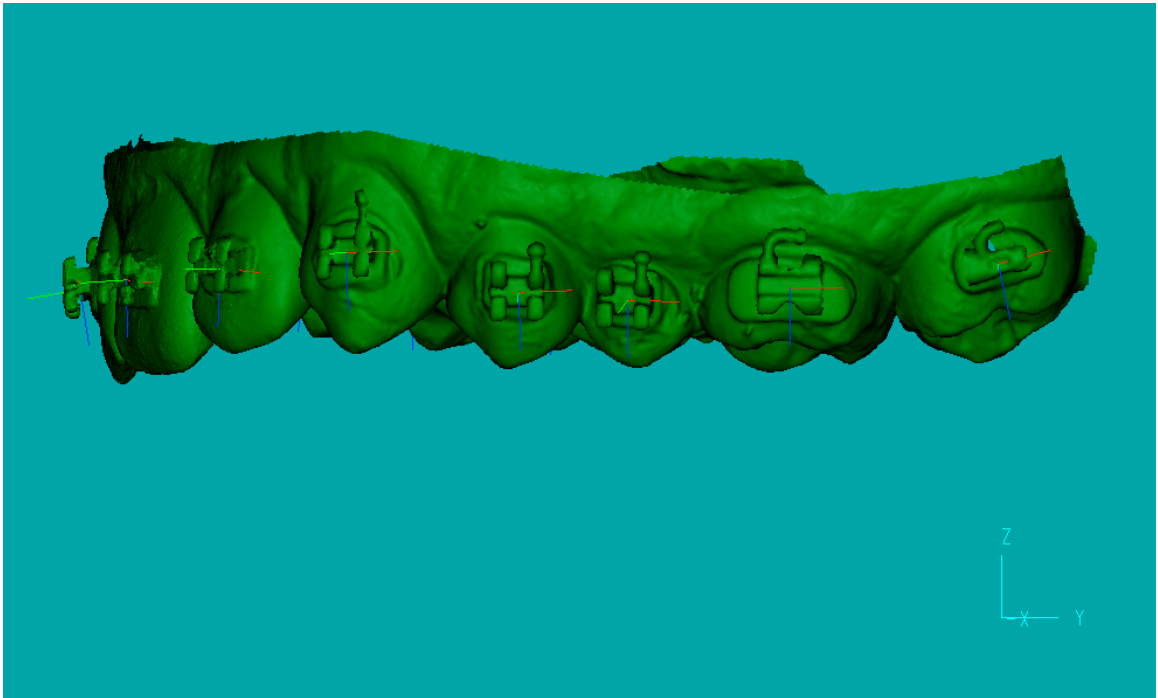


Figure 9: Bracket coordinates registered to an entire arch. A three-dimensional coordinate system was registered to each bracket individually to describe its precise location in space.

The software was used to compare bracket position between the pre-transfer and post-transfer models for each tooth. This was achieved by computing changes in the three-dimensional position of the pre-transfer bracket axis to the post-transfer bracket axis for each tooth to the nearest 1 μm . Discrepancies were quantified for both magnitude and direction. The pre-transfer bracket position was considered as baseline or “zero”, and any discrepancies in post-transfer bracket position were measured from the baseline position. Differences in pre-transfer and post-transfer bracket positions were quantified six dimensions (Figures 10 and 11).

- a. Mesiodistal (MD): a linear (mm) measurement of movement along the x-axis. A distal translation was reported as a positive number, and a mesial translation was reported as a negative number.
- b. Occlusolingival (OG): a linear (mm) measurement of movement along the z-axis. A gingival translation was reported as a positive number, and an occlusal translation was reported as a negative number.
- c. Buccolingual (BL): a linear (mm) measurement of movement along the y-axis. A lingual translation was reported as a positive number, and a buccal translation was reported as a negative number.

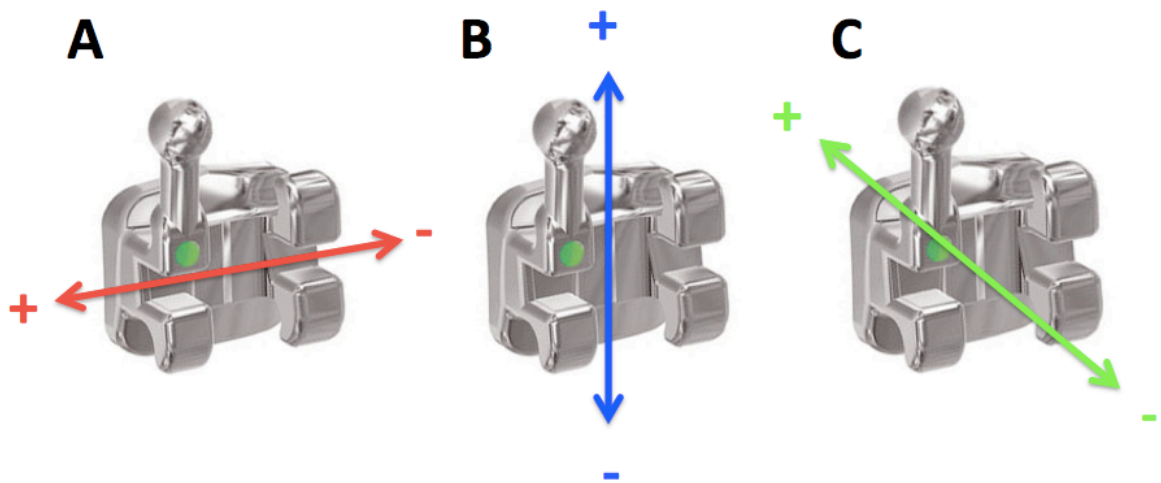


Figure 10: Measurement of translational bracket discrepancies. Changes in (A) mesiodistal, (B) occlusolingival, and (C) buccolingual position were measured in millimeters.

- d. Torque: an angular (degree) measurement of rotation about the x-axis. A lingual torque was reported as a positive number, and a labial torque was reported as a negative number.
- e. Rotation: an angular (degree) measurement of rotation about the z-axis. A rotation of the facial surface towards the distal was reported as a positive number, and a rotation of the facial surface towards the mesial was reported as a negative number.
- f. Tip: an angular (degree) measurement of rotation about the y-axis. A distal tip was reported as a positive number, and a mesial tip was reported as a negative number.

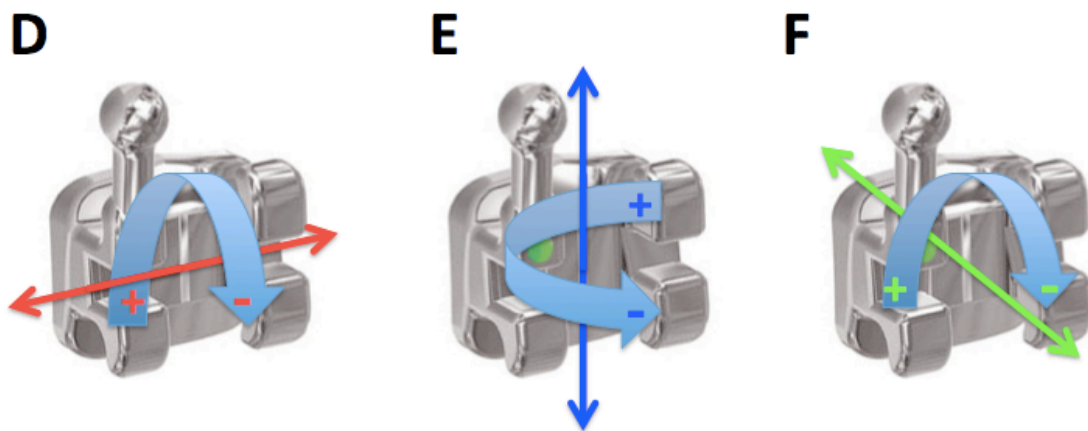


Figure 11: Measurement of rotational bracket discrepancies. Changes in (D) torque, (E) rotation, and (F) tip were measured in degrees.

For the repeatability portion of the study, each of the four bracketed stone arches were scanned twice. For each arch, these two scans were superimposed and the bracket coordinate systems registered and compared as described above.

Statistical Analysis:

Descriptive statistics (sample size, mean and standard deviation, minimum, maximum) were calculated for the six positional discrepancy measurements for both the raw data and the absolute values. Analysis of the raw data allowed appreciation of the direction of discrepancy, whereas analysis of the absolute values allowed appreciation of the overall magnitude of discrepancy. Linear discrepancies greater than 0.5mm and angular discrepancies greater than 3 degrees were considered clinically significant. These threshold values are based upon accepted professional standards. During completed case evaluation using the American Board of Orthodontics (ABO) objective grading system, points are subtracted for teeth that deviate 0.5mm or more from proper alignment and marginal ridge height.¹⁷ A crown-tip inadequacy of 3° causes a marginal ridge discrepancy of 0.5mm in an average-sized premolar.¹⁸

To determine if the discrepancy values exceeded the level of clinical significance, two one-sided tests of equivalence were performed for the six positional discrepancy values. Threshold values for equivalence testing were set at ± 0.5 for linear discrepancies and $\pm 3^\circ$ for angular discrepancies. A 90% confidence interval was used to determine if the final bracket position met the threshold. Bootstrap method for non-normal data was used to construct a 95% confidence interval for both lower and upper bounds.

To allow visualization of the direction of the discrepancy, histogram plots were generated for each of the six dimensions. To compare discrepancy values between the two tray methods, an independent samples t-test was performed on the mean of the absolute values ($\alpha=0.05$). ANOVA was performed on the mean of the absolute values

($\alpha=0.05$) to determine if there were any significant differences in bracket position discrepancy by tooth type. Linear mixed model was used to account for within-subject correlation.

For the repeatability portion of the study, the measured bracket error was compared to a gold stand of “zero”. Since two scans were taken of an identical model, there should theoretically be zero difference in bracket position (null hypothesis). Any bracket position difference detected was assumed to be from scanner or human error. To determine if this error was statistically significant, a random-intercept model was used to compare the error values to zero. This model was used to account for within-subject correlation, and is similar to a one-sample t-test.

Statistical analysis was performed using SAS 9.3 (SAS Institute, Cary, NC, USA).

Results

Descriptive statistics:

A total of 228 teeth were analyzed. For the transparent tray system, a total of 11 arches and 131 teeth were bonded; 2 bracket failures occurred leaving 129 teeth to be analyzed. For the opaque tray system, a total of 12 arches and 101 teeth were bonded; 2 bracket failures occurred leaving 99 teeth to be analyzed. The calculated bracket failure rate for both tray methods was just under 2%.

Tooth type	N teeth total	Transparent tray	Opaque tray
U1	14	10	4
U2	14	10	4
U3	12	8	4
U4	10	8	2
U5	13	10	3
U6	17	6	1
U7	6	6	0
L1	29	12	17
L2	29	12	17
L3	29	12	17
L4	25	10	15
L5	25	12	13
L6	10	8	2
L7	5	5	0
TOTAL	228	129	99

Table 1: Sample sizes by tooth type. Values are reported for all teeth and by tray type.

TABLE 2			Tray Type	
Dimension	Descriptive	All Teeth (N=228)	Transparent (N=129)	Opaque (N=99)
MD (mm)	Mean (SD)	0.04 (0.10)	0.02 (0.11)	0.06 (0.10)
	(Min, Max)	(-.25, 0.35)	(-.25, 0.30)	(-.14, 0.35)
BL (mm)	Mean (SD)	-.06 (0.12)	-.02 (0.08)	-.11 (0.14)
	(Min, Max)	(-.64, 0.21)	(-.41, 0.21)	(-.64, 0.12)
OG (mm)	Mean (SD)	-.08 (0.18)	-.02 (0.12)	-.17 (0.20)
	(Min, Max)	(-.90, 0.39)	(-.35, 0.39)	(-.90, 0.21)
Tip (°)	Mean (SD)	-.18 (1.85)	-.03 (1.72)	-.38 (2.00)
	(Min, Max)	(-6.49, 5.69)	(-6.49, 5.69)	(-5.31, 4.90)
Torque (°)	Mean (SD)	0.25 (1.71)	-.18 (1.26)	0.81 (2.04)
	(Min, Max)	(-6.13, 7.93)	(-6.13, 3.96)	(-4.80, 7.93)
Rotate (°)	Mean (SD)	0.12 (1.58)	0.06 (1.48)	0.20 (1.72)
	(Min, Max)	(-5.97, 8.12)	(-5.97, 4.05)	(-4.78, 8.12)

Table 2: Descriptive statistics for raw data (sample size, mean and standard deviation, minimum, maximum). Discrepancy values are reported for each of the six dimensions measured. Statistics are reported for all teeth and by tray type.

For the raw data summarized in Table 2, recall that the mean values reveal the general direction of discrepancy. Note that the mean values all approach zero. This is because the discrepancies are generally evenly distributed; thus, the average of the positive and negative numbers is approximately zero. However, there is a slight skewing of some of the means away from zero.

TABLE 3			Tray Type	
Dimension	Descriptive	All Teeth (N=228)	Transparent (N=129)	Opaque (N=99)
MD (mm)	Mean (SD)	0.08 (0.07)	0.08 (0.07)	0.09 (0.07)
	(Min, Max)	(0.00, 0.35)	(0.00, 0.30)	(0.00, 0.35)
BL (mm)	Mean (SD)	0.08 (0.11)	0.05 (0.07)	0.12 (0.14)
	(Min, Max)	(0.00, 0.64)	(0.00, 0.41)	(0.00, 0.64)
OG (mm)	Mean (SD)	0.14 (0.14)	0.09 (0.09)	0.19 (0.17)
	(Min, Max)	(0.00, 0.90)	(0.00, 0.39)	(0.00, 0.90)
Tip (°)	Mean (SD)	1.30 (1.33)	1.15 (1.27)	1.48 (1.39)
	(Min, Max)	(0.00, 6.49)	(0.00, 6.49)	(0.00, 5.31)
Torque (°)	Mean (SD)	0.75 (1.56)	0.51 (1.17)	1.06 (1.92)
	(Min, Max)	(0.00, 7.93)	(0.00, 6.13)	(0.00, 7.93)
Rotate (°)	Mean (SD)	0.83 (1.35)	0.83 (1.22)	0.84 (1.51)
	(Min, Max)	(0.00, 8.12)	(0.00, 5.97)	(0.00, 8.12)

Table 3: Descriptive statistics for absolute value data (n value, mean and standard deviation, minimum, maximum). Discrepancy values are reported for each of the six dimensions measured. Statistics are reported for all teeth and by tray type.

For the absolute value data summarized in Table 3, recall that the mean values reveal the magnitude of discrepancies. This number is more salient clinically, because we generally are more concerned with the magnitude of the discrepancy rather than the direction.

Equivalence testing:

In order to determine if the discrepancy values exceeded the level of clinical significance, two one-sided tests of equivalence were performed for the six positional

discrepancy values. Threshold values for equivalence testing were set at ± 0.5 for linear discrepancies and $\pm 3^\circ$ for angular discrepancies. A 90% confidence interval was used to determine if the final bracket position met the threshold. Bootstrap method was used to construct a 95% confidence interval for both lower and upper bounds.

TABLE 4				Bootstrap	
Dimension	Mean	90% CL of Mean	P-value	95% CL of lower bound	95% CL of upper bound
MD	0.0378	(0.03, 0.05)	<0.0001	(0.01, 0.05)	(0.03, 0.07)
BL	-0.0631	(-0.08, -0.05)	<0.0001	(-0.12, -0.04)	(-0.09, -0.02)
OG	-0.0829	(-0.10, -0.06)	<0.0001	(-0.14, -0.06)	(-0.10, -0.03)
Tip	-0.1786	(-0.38, 0.02)	<0.0001	(-0.70, -0.14)	(-0.26, 0.25)
Torque	0.2475	(0.06, 0.43)	<0.0001	(-0.18, 0.29)	(0.14, 0.68)
Rotate	0.1204	(-0.05, 0.29)	<0.0001	(-0.27, 0.15)	(0.07, 0.50)

Table 4: Equivalence testing for overall data.

		TABLE 5			Bootstrap	
Tray Type	Dimension	Mean	90% CL of Mean	P-value	95% CL of lower bound	95% CL of upper bound
Transparent	MD	0.0221	(0.01, 0.04)	<0.0001	(-0.02, 0.04)	(0.01, 0.07)
	BL	-0.0237	(-0.04, -0.01)	<0.0001	(-0.08, -0.01)	(-0.05, 0.01)
	OG	-0.0164	(-0.03, 0.00)	<0.0001	(-0.08, -0.00)	(-0.04, 0.04)
	Tip	-0.0267	(-0.28, 0.22)	<0.0001	(-0.81, 0.08)	(-0.21, 0.52)
	Torque	-0.1814	(-0.37, 0.00)	<0.0001	(-0.76, -0.09)	(-0.26, 0.24)
	Rotate	0.0604	(-0.16, 0.28)	<0.0001	(-0.47, 0.10)	(-0.03, 0.50)
Opaque	MD	0.0583	(0.04, 0.07)	<0.0001	(0.01, 0.07)	(0.04, 0.10)
	BL	-0.1143	(-0.14, -0.09)	<0.0001	(-0.20, -0.07)	(-0.15, -0.04)
	OG	-0.1694	(-0.20, -0.14)	<0.0001	(-0.25, -0.14)	(-0.18, -0.08)
	Tip	-0.3765	(-0.71, -0.04)	<0.0001	(-1.02, -0.43)	(-0.33, 0.28)
	Torque	0.8063	(0.47, 1.15)	<0.0001	(0.07, 0.81)	(0.62, 1.53)
	Rotate	0.1987	(-0.09, 0.49)	<0.0001	(-0.49, 0.22)	(0.06, 0.86)

Table 5: Equivalence testing by tray type.

The results show that all discrepancy values fall below the threshold, for both the data as a whole and for the transparent and opaque trays separately ($p < 0.0001$). This indicates that the discrepancy values detected fall below the level of clinical significance chosen. Therefore, for specific aim #1 we are able to accept the null hypothesis that there is no difference between pre-transfer and post-transfer bracket position.

A p-value of < 0.05 indicates that the lower bound is equal to or larger than the lower threshold (-0.5mm or -3 degrees), and that the upper bound is equal to or less than the upper threshold (0.5mm or 3 degrees). A 95% confidence interval has been generated for each of the discrepancy values.

Directional patterns of error: Histogram plots were generated to illustrate the direction of the errors detected for each of the six dimensions.

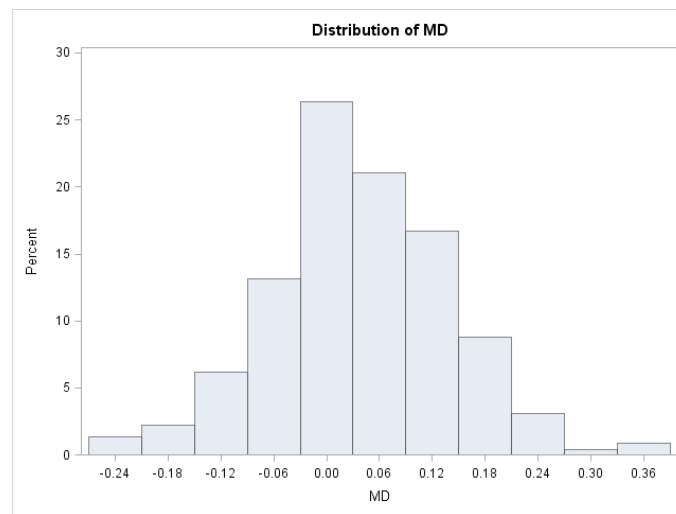


Figure 12a: Histogram plot for mesiodistal discrepancy. Negative values represent a mesial translation and positive values represent a distal translation. From this plot it seems the data is not significantly skewed in either direction.

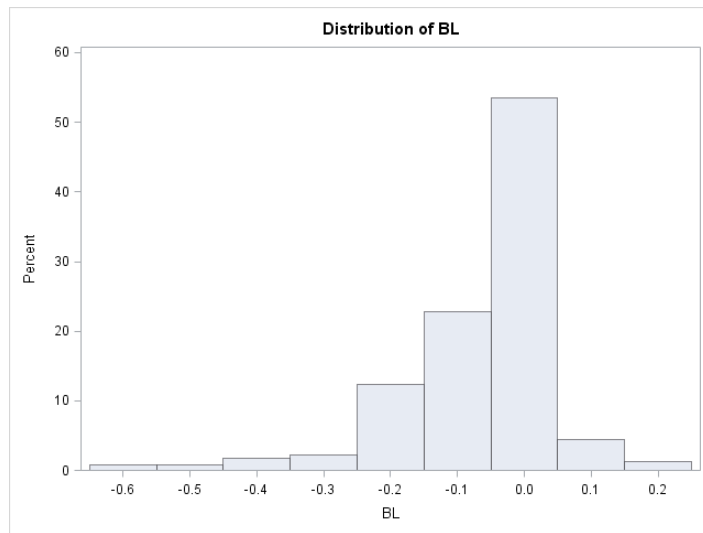


Figure 12b: Histogram plot for buccolingual discrepancy. Negative values represent a buccal translation and positive values represent a lingual translation. From this plot it seems the data is skewed towards the buccal.

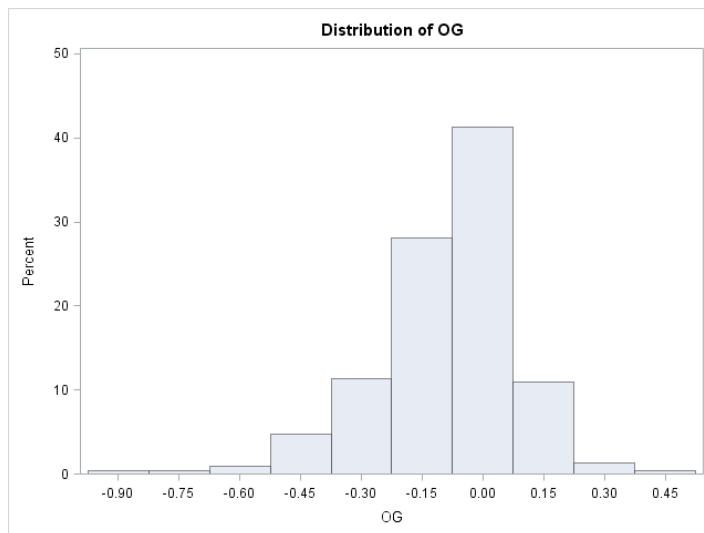


Figure 12c: Histogram plot for occlusogingival discrepancy. Negative values represent an occlusal translation and positive values represent a gingival translation. From this plot it seems the data is skewed towards the occlusal.

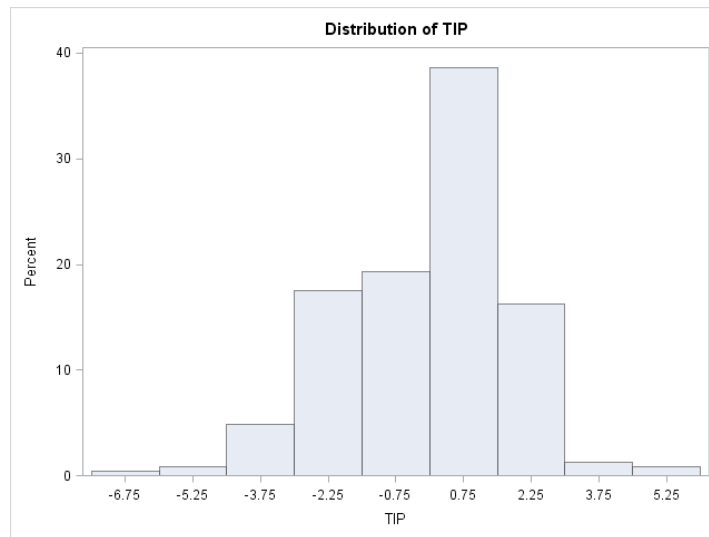


Figure 12d: Histogram plot for tip discrepancy. Negative values represent a mesial tip and positive values represent a distal tip. From this plot it seems the data is not significantly skewed in either direction.

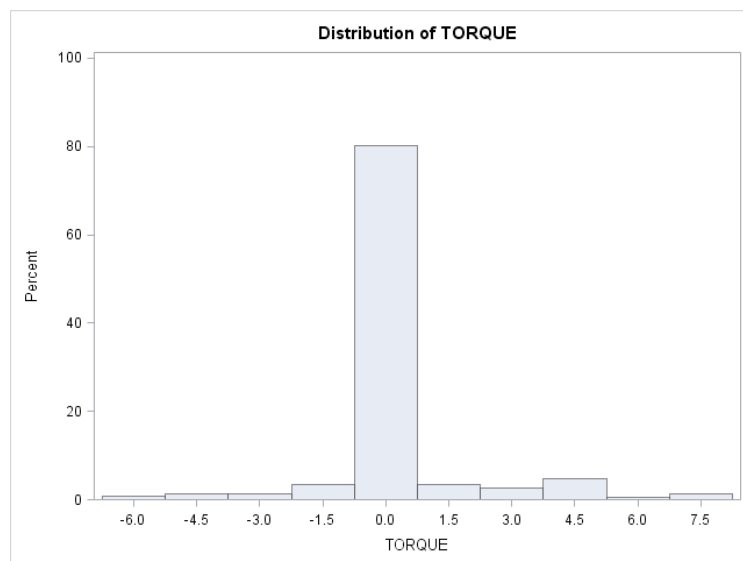


Figure 12e: Histogram plot for torque discrepancy. Negative values represent a labial torque and positive values represent a lingual torque. From this plot it seems the data is not significantly skewed in either direction.

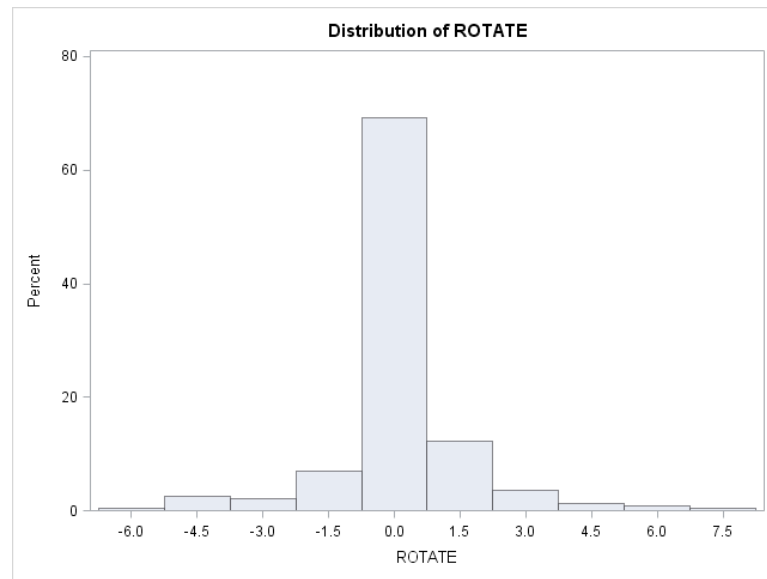


Figure 12f: Histogram plot for rotation discrepancy. Negative values represent mesial rotation and positive values represent a distal rotation. From this plot it seems the data is not significantly skewed in either direction.

Transparent vs. opaque trays: An independent samples t-test was performed on the mean of the absolute values ($\alpha=0.05$) to determine if there were any significant differences in bracket position discrepancy between the transparent versus opaque tray groups.

Variable	TABLE 6		Difference		
	Clear	Opaque	Difference (SE)	95% CI of Diff	P-value
MD	0.08(0.0091)	0.09(0.0095)	-0.00(0.0131)	(-0.0295, 0.0222)	0.7792
BL	0.05(0.0197)	0.10(0.0194)	-0.05(0.0277)	(-0.1072, 0.0020)	0.0589
OG	0.09(0.0198)	0.19(0.0201)	-0.09(0.0282)	(-0.1488, -0.0375)	0.0011
TIP	1.14(0.1574)	1.48(0.1667)	-0.34(0.2293)	(-0.7930, 0.1108)	0.1383
Torque	0.53(0.1692)	1.02(0.1820)	-0.49(0.2485)	(-0.9810, -0.0013)	0.0494
Rotate	0.82(0.1822)	0.89(0.1885)	-0.07(0.2621)	(-0.5903, 0.4432)	0.7793

Table 6: T-test for transparent vs. opaque trays

There is a statistically significant difference between the two tray types in the occlusogingival dimension ($p=0.0011$) and in the torque dimension ($p=0.0494$). Specifically, the magnitude of the discrepancy is greater in the opaque group for both measurements. For the occlusogingival dimension, the direction of the discrepancy for both tray types is negative or occlusal according to Table 2. For the torque dimension, the direction of discrepancy is slightly negative or labial for the transparent tray group and slightly positive or lingual for the opaque tray group according to Table 2.

Comparison between tooth type: ANOVA analysis was performed on the mean of the absolute values ($\alpha=0.05$) to determine if there were any significant differences in bracket position discrepancy by tooth type.

Tooth Type	MD	BL	OG	TIP	Torque	Rotate
U7	0.17(0.0292)	0.12(0.0417)	0.12(0.0561)	-0.88(0.7668)	0.15(0.6479)	0.25(0.5644)
U6	0.12(0.0270)	0.09(0.0388)	0.14(0.0521)	0.09(0.7091)	0.14(0.5990)	0.91(0.5219)
U5	0.11(0.0200)	0.12(0.0299)	0.21(0.0397)	-0.05(0.5218)	1.17(0.4428)	0.61(0.3863)
U4	0.07(0.0227)	0.14(0.0333)	0.21(0.0445)	-0.10(0.5946)	0.43(0.5036)	0.64(0.4390)
U3	0.07(0.0208)	0.07(0.0307)	0.16(0.0409)	0.28(0.5429)	0.12(0.4600)	0.25(0.4011)
U2	0.09(0.0193)	0.09(0.0291)	0.13(0.0386)	0.60(0.5034)	0.45(0.4278)	1.06(0.3733)
U1	0.12(0.0193)	0.09(0.0291)	0.09(0.0386)	0.01(0.5034)	0.75(0.4278)	0.28(0.3733)
L7	0.05(0.0316)	0.04(0.0441)	0.21(0.0595)	-0.84(0.8359)	1.56(0.7021)	1.05(0.6107)
L6	0.06(0.0226)	0.06(0.0327)	0.14(0.0438)	-0.73(0.5927)	0.36(0.5003)	0.61(0.4358)
L5	0.07(0.0145)	0.05(0.0231)	0.12(0.0303)	0.03(0.3772)	0.85(0.3219)	1.04(0.2813)
L4	0.08(0.0145)	0.06(0.0231)	0.15(0.0303)	0.21(0.3772)	0.76(0.3219)	0.91(0.2813)
L3	0.08(0.0136)	0.06(0.0220)	0.15(0.0287)	-0.49(0.3506)	1.26(0.2999)	1.31(0.2622)
L2	0.07(0.0136)	0.10(0.0220)	0.12(0.0287)	-0.22(0.3506)	0.82(0.2999)	0.74(0.2622)
L1	0.09(0.0136)	0.08(0.0220)	0.12(0.0287)	-0.78(0.3506)	0.69(0.2999)	0.94(0.2622)
P-value	0.1157	0.2614	0.2945	0.5896	0.6137	0.5989

Table 7: ANOVA to compare tooth types.

There does not seem to be any statistically significant differences in bracket position discrepancy between tooth type.

Repeatability data: To quantify the extent of operator error in the process of model scan and analysis, the repeatability error values were compared to a gold standard of zero using a random-intercept model. A total of 50 teeth were analyzed, which represents 21.9% of the original sample size.

Variable	Mean	Std Dev	Minimum	Maximum
MD (mm)	-0.013	0.063	-0.14	0.151
BL (mm)	0.025	0.055	-0.076	0.212
OG (mm)	0.009	0.05	-0.112	0.143
TIP (°)	0.478	1.602	-2.876	4.292
TORQUE (°)	0.36	1.94	-4.217	4.931
ROTATE (°)	0.453	1.843	-3.959	6.939

Table 8: Descriptive statistics for repeatability data

Dimension	Mean (95% Confidence Interval)	P-value
MD (mm)	-0.0129 (-0.0309, 0.0051)	0.1564
BL (mm)	0.02645 (-0.1477, 0.2006)	0.3043
OG (mm)	0.0085 (-0.1296, 0.1466)	0.5770
TIP (°)	0.4779 (0.0225, 0.9332)	0.0401
TORQUE (°)	0.3605 (-0.1909, 0.9118)	0.1950
ROTATE (°)	0.4532 (-0.0705, 0.9768)	0.0883

Table 9: Random-intercept testing for repeatability data

From this analysis, it seems that operator measurement error is only significant for the tip dimension, which showed a mean error of 0.4779°.

Discussion:

The theoretically more ideal bracket placement achieved in indirect bonding is of no use to the orthodontist unless the bracket position in the set-up is transferred accurately to the patient's dentition. Previously, it had simply been assumed that the indirect bonding transfer method was accurate. However, until now there had been only one other in-vivo study to support this assumption. The current study provides further evidence for the positional integrity of bracket placement during the indirect bonding transfer method.

Additionally, our study found a bonding appointment bracket failure rate of 2% at placement for both transfer methods. Based on the results of this study, practitioners can feel confident that when they use an indirect bonding system in their office it will be both accurate and efficient.

Specific Aim #1: Comparison of pre-transfer and post-transfer bracket position

The results of this study show that the indirect bonding transfer methods used in this study were accurate in reproducing the pre-transfer bracket position onto the patient's dentition in vivo at a clinically acceptable level ($p < 0.0001$). Although slight discrepancies did exist, they did not exceed the levels of clinical significance chosen ($\pm 0.5\text{mm}$ and $\pm 3^\circ$) for any of the six dimensions measured. Both tray methods investigated were found to be accurate ($p < 0.0001$). Therefore, for specific aim #1 we accept the null hypothesis that there is no difference between pre-transfer and post-transfer bracket position. This confirms the findings of the study performed by Lee¹⁴.

Specific Aim #2: Directional patterns of error

Analysis of bracket position in six dimensions of space showed that there was no clinically significant difference in bracket position in any of the dimensions. However, slight discrepancies did exist between the pre-transfer and post-transfer bracket position, and although not clinically significant it is still of interest to consider these discrepancies. Notably, it was found that compared to the pre-transfer position, the post-transfer bracket position tended to be more buccal (mean=0.08mm) and more occlusal (mean=0.10mm). Therefore, for specific aim #2 we reject the null hypothesis and accept the alternative hypothesis that there is a predictable directional pattern of error in bracket position differences.

This makes logical sense when considering the steps involved in the chairside indirect bonding procedure. Before the trays are seated onto the teeth, a layer of bond-enhancing primer is applied to both the bracket and the tooth surface. Therefore, a thin layer of adhesive is added in the buccolingual dimension, causing the bracket to protrude slightly buccally from the tooth surface. In addition, some practitioners have experienced anecdotally that the final bracket position may be more occlusal if the transfer tray is not fully seated or if inadequate finger pressure is applied to hold the tray in place during the curing process.

This partially confirms the findings of the study performed by Lee¹⁴, which also found a bracket error discrepancy towards the buccal. Interestingly, our results show an opposite direction of error for the occlusogingival dimension. The Lee¹⁴ study showed an error tendency towards the gingival whereas our study shows an error tendency towards

the occlusal. Since their study utilized the same opaque putty trays as the present study, this difference cannot be attributed to the tray material studied; rather, it is more likely due to differences in operator technique. In particular, the level of finger pressure when seating the trays could have caused this difference. In our study, perhaps the seating pressure used was too light, preventing the brackets from seating to their proper occlusogingival dimension. Ultimately, it is reassuring to know that slight variations in seating technique do not impact bracket position at a clinically significant level.

Specific Aim #3: Comparison of error between transparent and opaque trays

While not clinically significant for either tray group, our results show that the discrepancy tendency towards the occlusal and buccal was greater for the opaque tray group. There was also a significantly greater amount of torque discrepancy for the opaque group. Therefore, we reject the null hypothesis and accept the alternative hypothesis that there is a difference in bracket transfer error between the two systems.

Occlusal error: The opaque tray group exhibited a mean occlusal displacement of 0.19mm compared to a displacement of 0.09mm for the transparent group. This difference was statistically significant at $p=.0011$ ($\alpha=0.05$). One potential explanation for this difference is the longer curing time required for the chemical-cure primer used in the opaque tray system. For the opaque tray method, the tray is initially seated onto the teeth and held with light finger pressure for two minutes. After two minutes, the finger pressure is removed and the tray is maintained over the teeth for an additional four minutes to ensure full cure. It is feasible that it would be difficult to maintain full seating

of the tray even during the initial two minutes, and that after removal of light finger pressure the tray might unseat slightly during the remainder of the cure. In contrast, set of the light-cure primer was achieved in approximately 20-30 seconds with a curing light while the tray is held the entire time with light finger pressure.

Buccal error: The opaque tray group exhibited a mean buccal displacement of 0.10mm compared to a displacement of 0.05mm for the transparent group. This difference approached statistical significance at $p=.0589$ ($\alpha=0.05$). This might be explained by the fact that the chemical-cure primer used in the opaque tray method is thicker and more viscous than the light-cure primer used in the transparent tray group. Still, the discrepancy did not reach the clinically significant threshold for either tray group.

Torque error: The brackets in the opaque tray group exhibited a mean lingual crown torque of 1.02^0 compared to a lingual crown torque of 0.53^0 for the transparent group. That is, the brackets in the opaque tray group were further out buccally from the tooth on the gingival aspect compared to transparent tray group. Note that although this is denoted as lingual crown torque of the bracket itself, such a position would actually cause buccal crown torque movement to the tooth. This difference was statistically significant at $p=.0494$ ($\alpha=0.05$). It is postulated that this could also be related to the primer used in the opaque tray system. A slight lingual crown torque to the bracket would be created if the thickness of the primer were greater at the gingival portion of the bracket compared to the occlusal portion. Since practitioners are instructed to brush the primer on from gingival to occlusal, it is feasible that more primer is deposited initially at the gingival

and thinned as the brush brings the primer towards the occlusal. Perhaps because the chemical-cure primer is thicker it is more difficult to distribute evenly along the tooth surface.

Another explanation for the increased lingual crown torque in the opaque tray group could be the difference in tray trimming technique. The opaque trays were trimmed to the gingival aspect of the brackets in order to reduce the chance of bracket failure during tray removal due to the stiff nature of the tray. The transparent trays, which are slightly more flexible, were trimmed near the gingival margin. As a result, the more gingival coverage of the transparent trays could have seated the gingival aspect of the brackets further against the tooth, resulting in less relative lingual crown torque of the bracket. Again, the discrepancy in torque was very slight and did not nearly approach the level of clinical significance.

While both the transparent and opaque tray methods have proven to be clinically acceptable in transferring the indirect bracket position in all six dimensions, it seems there might be a slight advantage to using a light-cure primer. Specifically, the lower viscosity of the primer seems to allow for less displacement of the bracket away from the tooth surface during bonding. Also, it may be easier to achieve a more even distribution of primer over the tooth surface compared to the more viscous chemical-cure primer. Finally, there may be an advantage to using the light-cure primer because set is quicker and easier to achieve, and the possibilities for unseating of the tray during the curing process are therefore minimized.

Strengths and Limitations

The present study has several strengths and some weaknesses. Compared to previous literature on indirect bonding, our study has a major advantage in that it is one of the first to perform the indirect bonding procedure in vivo on real patients. From start to finish, all clinical procedures exactly represented indirect bonding in an orthodontic office. Previous studies had used stone models or manikins, and thus did not factor in important clinical complications such as patient anatomy and behavior, moisture contamination, etc. It is understandably more difficult to achieve an accurate transfer when working in an actual patient's mouth. Therefore, we can say with confidence that our results are clinically salient.

Secondly, our study is one of the first to utilize digital three-dimensional technology to perform analysis of bracket position. Previous studies had used photographs for measurement or measured directly on models. One of the biggest advantages in using digital technology is the ability to measure positional changes on a much smaller scale than is possible with traditional measurement tools. Our software was able to compute three-dimensional changes to the nearest 1 μm . This level of sensitivity would be virtually impossible with non-digital technology. This allowed us to detect minor differences that would likely not be recognized with other methods of measurement. Furthermore, with the use of 3D digital models it is possible to quantify changes in six degrees of space. Using traditional measurement tools it is simple to measure linear discrepancies (mesiodistal, occlusogingival) but it is much harder to recognize angular discrepancies such as tip, torque, and rotation.

To our knowledge, our study is the first in-vivo study that includes more than one indirect bonding system for analysis. Currently there are numerous indirect bonding in-house tray systems available on the market, and there has been a recent rise in digital indirect bonding systems that deliver laboratory fabricated trays. The results of our study confirm the results of Castilla et. al¹⁵ which showed that while there are minor differences between the accuracy of different transfer tray systems, all systems achieve a level of clinically acceptable accuracy. Therefore, it seems reasonable to conclude that we can generalize our results to any indirect bonding system.

Finally, although the six practitioners in this study were orthodontic residents, it was advantageous to include multiple operators to account for the occurrence of human error. Even though the operators were slightly inexperienced and with varying level of skill, the results show that the indirect bonding transfer method was still accurate.

However, this study is not without limitations. This was not a longitudinal study—the subjects' participation in the study ended after the bonding appointment. It would have been interesting to follow the patients to determine the long-term bracket survival rate, and possibly the need for future bracket repositioning.

In addition, the digital superimposition process was slightly affected by the presence of the brackets on the models. That is, the superimposition may have favored better approximation of the brackets and decreased the level of reported discrepancy. However, since the superimposition was based largely on tooth surface area rather than bracket surface area, it is reasonable to assume that the effect was minor. Visual analysis of each superimposition supported this assumption. It would be advantageous, however,

to perform a study in which the superimposition is performed disregarding the bracket position.

Finally, there were several potential sources of error in the bracket comparison process. First, there is some inherent error involved with the model capture and digitization using an intraoral scanner. Recent literature has shown that this scanner produces a clinically accurate representation of the patient's dentition when compared with models obtained from traditional alginate impressions, however there are minor errors in the capture of tooth position and arch width.¹⁶ The scanning error was found to be .02mm for maxillary teeth and .01mm for mandibular teeth.¹⁶ Since this level of error is greater than our comparison measurement unit of 1um, it decreases the level of sensitivity at which bracket position differences can be detected. Secondly, there is error involved with the superimposition process—while the surface area matching was extensive at 50 iterations of closest point matching, it was not infinite. Finally, there is human error involved with the placement of the bracket coordinate system. Our statistical analysis revealed that all these potential sources of inaccuracy taken together resulted in very minor levels of measurement error. The error was only significant in the tip dimension.

The results of this study are reassuring to the increasing number of orthodontists who are implementing indirect bonding systems into their offices. This study provides evidence for the positional integrity of two indirect bonding transfer tray systems, and we reasonably believe that the results can be generalized to other systems, both in-house and commercial.

Conclusions:

- Both indirect bonding transfer methods investigated in this study were found to be accurate within the clinically acceptable boundaries of $\pm 0.5\text{mm}$ and $\pm 3^\circ$.
- Post-transfer bracket position tended to be slightly more towards the buccal and occlusal surfaces of the teeth for both methods.
- The opaque trays showed more pronounced bracket error towards the occlusal and buccal and more lingual crown torque error compared to the transparent trays.
- The bonding appointment bracket failure rate in this study was 2%.

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